



European Medicines Agency Recommends Marketing Approval of Gobivaz®, Alvotech's Proposed Biosimilar to Simponi® (golimumab) with Advanz Pharma as Commercialization Partner

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REYKJAVIK, ICELAND and LONDON, Sept. 22, 2025 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide and Advanz Pharma Holdco Limited ("Advanz Pharma"), a UK headquartered global pharmaceutical company with a strategic focus on specialty, hospital, and rare disease medicines in Europe, today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human use (CHMP) has adopted a positive opinion recommending approval for Gobivaz®, Alvotech's proposed biosimilar to Simponi® (golimumab), a biologic used to treat several chronic inflammatory diseases.

"We look forward to working with Advanz Pharma to increase access for patients and healthcare professionals to golimumab, as the reference biologic Simponi® is an important treatment option for a number of immune-mediated diseases," said Joseph McClellan, Chief Scientific and Technical Officer for Alvotech.

"The positive CHMP opinion for Gobivaz® is an important milestone in expanding patient access and marks a significant step forward in Advanz Pharma's ambition to build a leading biosimilars presence in Europe," said Nick Warwick, Chief Medical Officer, Advanz Pharma.

The CHMP opinion recommends granting of a marketing authorization for Gobivaz® 50 mg/0.5mL and 100mg/mL in a pre-filled syringe and autoinjector, for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis in adult patients and juvenile idiopathic arthritis across the 27 member states of the European Union, in addition to Norway, Iceland and Lichtenstein.

Gobivaz® remains under EMA regulatory review with a final decision by the European Commission pending.

Alvotech is responsible for the development and commercial supply of Gobivaz®. Advanz Pharma is responsible for registration and has exclusive rights for commercialization in Europe.

In April 2024 Alvotech announced positive top-line results from a confirmatory clinical study comparing efficacy, safety, and immunogenicity between its biosimilar candidate AVT05 and Simponi® (golimumab) in patients with moderate to severe rheumatoid arthritis. In November 2023, Alvotech announced positive topline results from a pharmacokinetic study which assessed the pharmacokinetics, safety, and tolerability of AVT05 compared to Simponi® in healthy adult participants.

About AVT05

AVT05 is a biosimilar candidate for Simponi® (golimumab) and Simponi Aria® (golimumab). Golimumab is a monoclonal antibody that inhibits tumor necrosis factor alpha (TNF alpha). Elevated TNF alpha levels have been implicated in several chronic inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis [1]. AVT05 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

Sources

[1] [Simponi product information](#)

Use of trademarks

Simponi® and Simponi Aria® are registered trademarks of Johnson & Johnson.

About Alvotech

Alvotech is a biotech company, founded by Robert Wessman, focused solely on the development and manufacture of biosimilar medicines for patients worldwide. Alvotech seeks to be a global leader in the biosimilar space by delivering high quality, cost-effective products, and services, enabled by a fully integrated approach and broad in-house capabilities. Alvotech's current pipeline includes eight disclosed biosimilar candidates aimed at treating autoimmune disorders, eye disorders, osteoporosis, respiratory disease, and cancer. Alvotech has formed a network of strategic commercial partnerships to provide global reach and leverage local expertise in markets that include the United States, Europe, Japan, China, and other Asian countries and large parts of South America, Africa and the Middle East. Alvotech's commercial partners include Teva Pharmaceuticals, a US affiliate of Teva Pharmaceutical Industries Ltd. (US), STADA Arzneimittel AG (EU), Fuji Pharma Co., Ltd (Japan), Advanz Pharma (EEA, UK, Switzerland, Canada, Australia and New Zealand), Cipla/Cipla Gulf/Cipla Med Pro (Australia, New Zealand, South Africa/Africa), JAMP Pharma Corporation (Canada), Yangtze River Pharmaceutical (Group) Co., Ltd. (China), DKSH (Taiwan, Hong Kong, Cambodia, Malaysia, Singapore, Indonesia, India, Bangladesh and Pakistan), YAS Holding LLC (Middle East and North Africa), Abdi Ibrahim (Turkey), Kamada Ltd. (Israel), Mega Labs, Stein, Libbs, Tuteur and Saval (Latin America) and Lotus Pharmaceuticals Co., Ltd. (Thailand, Vietnam, Philippines, and South Korea). Each commercial partnership covers a unique set of product(s) and territories. Except as specifically set forth therein, Alvotech disclaims responsibility for the content of periodic filings, disclosures and other reports made available by its partners. For more information, please visit www.alvotech.com. None of the information on the Alvotech website shall be deemed part of this press release.

About Advanz Pharma

Partner of choice in specialty, hospital, and rare disease medicines. Advanz Pharma is a global pharmaceutical company with the purpose to improve patients' lives by providing and enhancing the specialty, hospital, and rare disease medicines they depend on. Our headquarters are in London, UK. We have commercial sales in more than 90 countries globally and have a direct commercial presence in more than 20 countries, including key countries in Europe, the US, Canada, and Australia, a Centre of Excellence in Mumbai, India, as well as an established global distribution and commercialization partner network. Advanz Pharma's product portfolio and pipeline comprises innovative medicines, biosimilars & specialty generics, and originator brands. Our products cover a broad range of therapeutic areas, including hepatology, rheumatology, gastroenterology, anti-infectives,

critical care, endocrinology, oncology, CNS, and, more broadly, rare disease medicines. Our ambition is to be a partner of choice for the commercialization of specialty, hospital, and rare disease medicines in Europe, Canada, and Australia. In line with our ambition, we are partnering with biopharma and development companies to bring medicines to patients. We can only achieve this due to our dedicated and highly qualified employees, acting in line with our company values of entrepreneurship, speed, and integrity.

Alvotech Forward-Looking Statements

Certain statements in this communication may be considered “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements generally relate to future events or the future financial or operating performance of Alvotech and may include, for example, Alvotech’s expectations regarding future growth, results of operations, performance, future capital and other expenditures, competitive advantages, business prospects and opportunities including pipeline product development, future plans and intentions, results, level of activities, performance, goals or achievements or other future events, regulatory review and interactions, the satisfactory responses to the FDA’s inspection findings and resolution of other deficiencies conveyed following the re-inspection of Alvotech’s manufacturing site, the potential approval, including for AVT05, and the product candidates in scope of the partnership with Advanz, by the FDA and other regulatory agencies and commercial launch of its product candidates, the timing of the announcement of clinical study results, the commencement of patient studies, regulatory applications, approvals and market launches, and the estimated size of the total addressable market of Alvotech’s pipeline products. In some cases, you can identify forward-looking statements by terminology such as “may”, “should”, “expect”, “intend”, “will”, “estimate”, “anticipate”, “believe”, “predict”, “potential” or “continue”, or the negatives of these terms or variations of them or similar terminology. Such forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by Alvotech and its management, are inherently uncertain and are inherently subject to risks, variability, and contingencies, many of which are beyond Alvotech’s control. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (1) the ability to reach development milestones under commercial partnership agreements including the partnership with Advanz; (2) the ability to raise substantial additional funding, which may not be available on acceptable terms or at all; (3) the ability to maintain stock exchange listing; (4) changes in applicable laws or regulations; (5) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (6) Alvotech’s estimates of expenses and profitability; (7) Alvotech’s ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (8) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (9) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (10) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (11) the ability of Alvotech or its partners, including Advanz, to gain approval from regulators for planned clinical studies, study plans or sites; (12) the ability of Alvotech’s partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (13) Alvotech’s ability to obtain and maintain regulatory approval or authorizations of its products, including the timing or likelihood of expansion into additional markets or geographies; (14) the success of Alvotech’s current and future collaborations, joint ventures, partnerships or licensing arrangements, including the partnership with Advanz; (15) Alvotech’s ability, and that of its commercial partners, including Advanz, to execute their commercialization strategy for approved products; (16) Alvotech’s ability to manufacture sufficient commercial supply of its approved products; (17) the outcome of ongoing and future litigation regarding Alvotech’s products and product candidates; (18) the potential impact of the ongoing COVID-19 pandemic on the FDA’s review timelines, including its ability to complete timely inspection of manufacturing sites; (19) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, war in Ukraine and global geopolitical tension, on Alvotech’s business, financial position, strategy and anticipated milestones; and (20) other risks and uncertainties set forth in the sections entitled “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements” in documents that Alvotech may from time to time file or furnish with the SEC. There may be additional risks that Alvotech does not presently know or that Alvotech currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. Nothing in this communication should be regarded as a representation by any person that the forward-looking statements made herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. Alvotech does not undertake any duty to update these forward-looking statements or to inform the recipient of any matters of which any of them becomes aware of which may affect any matter referred to in this communication. 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Advanz Pharma Forward-Looking Statements

Certain statements in this press release are forward-looking statements. These statements may be identified by words such as “anticipate”, “expectation”, “belief”, “estimate”, “plan”, “target”, “project”, “will”, “may”, “should” or “forecast” and similar expressions, or by their context. Although Advanz Pharma believes that these assumptions were reasonable when made, by their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial consequences of the plans and events described herein. Actual results may differ from those set forth in the forward-looking statements as a result of various factors (including, but not limited to, future global economic conditions, changed market conditions affecting the industry, intense competition in the markets in which Advanz Pharma operates, costs of compliance with applicable laws, regulations and standards, diverse political, legal, economic and other conditions affecting Advanz Pharma’s markets, and other factors beyond the control of Advanz Pharma. Neither Advanz Pharma nor any of its directors, officers, employees, advisors, or any other person is under any obligation to update or keep current the information contained in this press release or revise any forward-looking statements, whether as a result of new information, future events or otherwise. You should not place undue reliance on forward-looking statements, which speak of the date of this press release. Statements contained in this press release regarding past trends or events should not be taken as a representation that such trends or events will continue in the future. No obligation is assumed to update any forward-looking statements. The information contained in this press release is provided as at the date of this document and is subject to change without notice.

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